Serial No. <u>10/581,158</u> Docket No. <u>4439-4043</u>

REMARKS

Claims 1-27 are pending after entry of this paper. Claims 5-6, 11-12, 17-18, and 23-24 were provisionally elected and claims 1-4, 7-10, 13-16, 19-22, and 25-27 were provisionally withdrawn in a Response to Restriction Requirement filed November 23, 2007.

Amendments to the Specification

An substitute Sequence Listing is submitted herewith in order to amend SEQ ID NOs. 17 and 18 in the Sequence Listing filed on May 31, 2006. Submitted herewith are the following: (1) text (.txt) file containing the computer readable Substitute Sequence Listing for the above-identified patent application; (2) a PDF "paper" copy of the Substitute Sequence Listing; and (3) a Statement Under 37 C.F.R. §1.825(b) indicating that the PDF copy is identical to the text (.txt) file of the Substitute Sequence Listing. Also, presented below is an explanation of the corrections and why the amended sequences do not constitute new matter, as well as evidence that the applicant was in possession of the invention prior to the filing of the PCT application. Entry of the Substitute Sequence Listing into the instant application is respectfully requested.

Sequence Listing

At the time of filing of the earliest priority application (Japanese Application No. 2003-401943, filed December 1, 2003), the applicant prepared DNA and amino acid sequences for human Sgo1 (SEQ ID NOs: 17 and 18, respectively), which contained

differences in the N-terminal region. This sequence was based on GenBank Accession number O9BVA8 data.

The complete and correct sequence of human Sgo1 was later determined by the applicant through cloning, and both the DNA and amino acid sequences (SEQ ID Nos. 17 and 18, respectively) were deposited at GenBank on September 22, 2004 under the accession numbers AB190994 and BAD91318, respectively (see NCBI/GenBank website printout submitted herewith) (Exhibit A). The date of the GenBank deposit precedes the PCT filing date (November 24, 2004) in addition to the filing date of the instant U.S. application. The Genbank sequence database is an internationally recognized sequence depository that Molecular Biologists routinely utilize for analyzing sequences.

Through an inadvertent error, the Sequence Listing, as originally filed in Japanese Application No. 2003-401943, on December 1, 2003, had not been amended with the correct sequences for SEQ ID Nos. 17 and 18 when the PCT application was filed, even though the applicant was in possession of the correct sequences prior to the PCT filling date. The Sgo1 protein length described in the instant specification is longer than the sequence that was submitted in the original Sequence Listing filed May 31, 2006 (compare 527 amino acids with 511 amino acids). Although the Sequence Listing was not amended when the PCT application was filed, the PCT specification and instant specification state in paragraph [0030], "The Sequencing revealed that the Sgo1 mRNA encodes a protein having 527 amino acids" (emphasis added). The number of amino acids referenced in paragraph [0030] corresponds to the correct number of amino acids for human Sgo1 protein (see Sequence Listing, SEQ ID No. 18, filed herewith). Thus,

the PCT application as well as the instant specification <u>as filed</u> disclose the correct amino acid length for human Sgo1 protein. The reference to human Sgo1 protein in paragraph [0030] confirms that the applicant was in possession of the sequence prior to filing the PCT application.

As further evidence that the applicant was in possession of the sequences prior to the filing of the instant application, an article co-authored by the applicant is based on the correct Sgo1 sequences (T.S. Kitajima, et al. "Human Bub1 defines the persistent cohesion site along the mitotic chromosome by affecting Shugoshin localization" *Current Biology*, Vol. 15, 2005; submitted herewith) (Exhibit B). The "Supplemental Experimental Procedures" section of this article states:

Because no information for the N-terminal amino acid sequence of human Sgo1 was available in the databases, we cloned a cDNA fragment by amplification from a cDNA library (BD Biosciences) with primers recognizing the cloning site of λTriplEx (5'-CTCGGGAAGCGCGCCATTGTG-3') and the DNA sequence corresponding to amino acids 237–242 of Q9BVA8 (5'-CCTGGCTGAATCAGCTTTGGTG-3'). Sequencing revealed that the Sgo1 mRNA encodes a 527 aa protein (page S1, left column, under "Cloning and Preparation of Antibodies").

The article shows that the biological material (i.e., the cDNA library) that was cloned and sequenced by the applicant was commercially available prior to the filing of the PCT application. Additionally, the authors disclosed the primers that were used for cloning which revealed that the Sgo1 mRNA encoded a 527 amino acid protein. Thus, a person of ordinary skill in the art would have (1) recognized that the sequences listed in the application as filed were incorrect, since the specification describes a protein containing 527 amino acids while the Sequence Listing disclosed a

protein sequence of only 511 amino acids and (2) a person of ordinary skill in the art would have been able to recognize how to determine the correct sequence since the biological material was publicly available and the authors described the cloning primer sequences in an article prior to filing the instant application.

The applicant only recently noticed that errors existed in the Sequence Listing while confirming the sequences in the application during a review of the Restriction Requirement issued on October 23, 2007.

The applicant asserts that no new matter is introduced with this amendment. The Examiner's attention is respectfully directed to the MPEP § 2163(I)(B), which states (in relevant part):

An amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of the error in the specification, but also recognize the appropriate correction. In re Oda. 443 F.2d 1200, 170 USPQ 268 (CCPA 1971). With respect to the correction of sequencing errors in applications disclosing nucleic acid and/or amino acid sequences, it is well known that sequencing errors are a common problem in molecular biology. See, e.g., Peter Richterich, Estimation of Errors in 'Raw' DNA Sequences: A Validation Study, 8 Genome Research 251-59 (1998)... Corrections of minor errors in the sequence may be possible based on the argument that one of skill in the art would have resequenced the deposited material and would have immediately recognized the minor error

Thus, according to the MPEP guidelines, the amended sequences (i.e., SEQ ID Nos. 17 and 18) do not constitute new matter. The applicant asserts that a person of ordinary skill in the art would have "not only recognize[d] the existence of the error in the specification, but also recognize[d] the appropriate correction" since (1) the

instant specification discloses that "Sgo1 mRNA encodes a protein having 527 amino acids" (emphasis added) while the Sequence Listing discloses a protein of only 511 amino acids; (2) the applicant made the correct sequences publicly available by submitting the sequences to an internationally recognized sequence depository, GenBank, prior to the filing of the PCT application; and (3) the biological sample was publicly available prior to filing the PCT application and the applicant disclosed the cloning primer sequences prior to filing the instant application.

CONCLUSION

Prior to examination and calculation of the filing fee, please amend the application as described above. Entry of the Substitute Sequence Listing into the instant application is respectfully requested.

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AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. 13-4500. Order No. 4439-4043.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 13-4500. Order No. 4439-4043.

Respectfully submitted, MORGAN & FINNEGAN, L.L.P.

Dated: January 16, 2008

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